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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,686	06/18/2001	Sandrine Segura	016800-445	9187

7590

01/15/2002

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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1619

DATE MAILED: 01/15/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/881,686

Applicant(s)

SEGURA ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claims 1-49 are pending.

Election/Restrictions

Claims 1-49 are generic to a plurality of disclosed patentably distinct species comprising oil-in-water emulsions comprising micronized biologically active agents. In particular, the oil-in-water emulsions comprise a discontinuous fatty phase, a continuous aqueous phase, a biologically active agent, an emulsifying system, a surfactant emulsifier, a co-surfactant, a pro-penetrating and/or wetting agent, a gelling agent, and furthermore the invention comprises various regimes. Possible discontinuous fatty phases include a poly(C1-C20) alkylsiloxane, a poly(C1-C20)alkylsiloxane containing trimethylsilyl endgroups, a linear polydimethylsiloxane, an alkylmethylpolysiloxane, a cetyldimethicone, a volatile silicone oil, a cyclic volatile silicone having from 3 to 8 silicon atoms, a cyclomethicone, a cyclotetradimethylsiloxane, a cyclopentadimethylsiloxane, a cyclohexadimethylsiloxane, a dimethylsiloxane/methylalkylsiloxane, hexamethyldisiloxane, hexyl heptamethyltrisiloxane, octyl heptamethyltrisiloxane, a phenylsilicone oil, isohexadecane, a liquid paraffin, a liquid petroleum jelly, an almond oil, a perhydrosqualene, an apricot oil, a wheat germ oil, a sweet almond oil, a beauty-leaf oil, a palm oil, a castor oil, an avocado oil, a jojoba oil, an olive oil, a cereal germ oil, diisopropyl adipate, octyldodecyl myristate, an acetyl glyceride, a decanoate, a ricinoleate, a fatty acid triglyceride, a glyceride, a hydrogenated polyisobutene, a lanolin, isohexadecane, dioctylcyclohexane, isopropyl palmitate, hydrogenated polyisobutene, diisopropyl adipate, dicaprylyl ether, isopropyl myristate, dipropylene glycol dipelargonate, cetostearyl isononanoate, cetostearyl ethylhexanoate, a synthetic squalene, olive oil, octyl

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palmitate, octyldodecyl myristate, and caprylic/capric triglycerides. Possible continuous aqueous phases include floral water, cornflower water, a thermal spring water, a natural mineral water, eau de Vittel, a water from the Vichy basin, eau de Uriage, eau de la Roched Posay, eau de la Bourboule, eau d'Enghien-les-Bains, eau de Saint Gervais-les-Bains, eau de Neris-les-Bains, eau d'Allevard-les-Bains, eau de Digne, eau de Maizieres, eau de Neyrac-les-Bains, eau de Lons-le-Saunier, Eaux Bonnes, eau de Rochefort, eau de Saint Christau, eau des Fumades, eau de Tercis-les-Bains, eau d'Avene, and eau d'Aix-les-Bains. Possible emulsifying systems include copolymerates of monoolefinically unsaturated C3-C6 carboxylic acid monomers and acrylic acid fatty esters, wherein the carboxylic acids are acrylic acid or methacrylic acid, and the acrylic esters are defined by the formula in claim 6. Possible surfactant emulsifiers include glyceryl, PEG-100 stearate, a polyoxyethylenated fatty acid ester, and a polyoxyethylenated stearyl alcohol combined with a polyethylenated stearyl alcohol. Possible co-surfactants include sorbitan ester, sorbitan sesquioleate, and sorbitan isostearate. Possible wetting agents include poloxamers, oxyethylenated sorbitol esters, polysorbate, propylene glycol, glycerol, and sorbitol. Possible pro-penetrating agents include propylene glycol, glycerol, and sorbitol. Gelling agents disclosed include a carboxyvinyl polymer, a xanthan gum, a guar gum, and a polyacrylamide. Possible active agents include nadifloxacin, 6-[7-(1-adamantyl)-6-methoxyethoxymethoxy-2-naphthyl]nicotinic acid, 6-[3-(1-adamantyl-4-hydroxyphenyl)2-naphthoic acid, 6-(3,5,5,8,8-pentamethyl-5,6,7,8-tetrahydro-2-naphthylthio)nicotinic acid, 3-(3,5,5,8,8-pentamethyl-5,6,7,8-tetrahydro-2-naphthyl)phenylacrylic acid, 2-hydroxy-4-[7-(1-adamantyl)-6-methoxyethoxymethoxy-2-naphthyl]benzoic acid, fluoroquinolones, rifamycin, josamycin, sulfadiazine, virginiamycin, fusidic acid, benzoyl peroxide, piroctone olamine, salicylic acid,

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vitamin E, crotamiton, vidarabine, griseofulvin, econazole, ketoconazole, miconazole, amphotericin B, terbinafine, piroctone olamine, clobetasone butyrate, hydrocortisone, gluocinolone acetonide, and betamethasone. Possible regimes include (1)-(17), listed on pages 30-32 of the specification. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Note: Applicant is respectfully requested to elect a specific discontinuous fatty phase, a specific continuous aqueous phase, a specific biologically active agent, a specific copolymerate (emulsify system), a specific surfactant emulsifier, a specific co-surfactant, a specific pro-penetrating and/or wetting agent, a specific gelling agent, and a specific regime within the elected group above for examination.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Norman Stepno on January 2, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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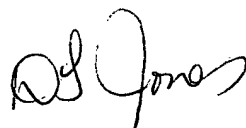
currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on T-F (6-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
January 8, 2002


DAMERON L. JONES
PRIMARY EXAMINER